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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/064,661

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Bruce W. Brodman

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12/04/2003

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EXAMINER

LILLING, HERBERT J

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 12/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

SM

Office Action Summary	Application No.	Applicant(s)	
	10/064,661	BRODMAN ET AL.	
	Examiner	Art Unit	
	HERBERT J LILLING	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) 3,5,6 and 8-15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4 and 7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 3, 5, 6 and 8-15 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

1. Receipt is acknowledged of the election response filed November 13, 2003.
2. Claims 1-15 remain pending in this application.
3. Applicant has elected with traverse, Group II, Claims 4 and 7 drawn to the microorganism *Burkholderia* sp (ATCC PTA-4111). Claims 1-2, 4 and 7 are readable on the elected invention.

Claims 3, 5-6 and 8-15 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected invention(s) or species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. November 13, 2003.

In accordance with the following paragraph, this Examiner will rejoin all processes within the scope as indicated.

F.P.: Ochiai/Brouwer Rejoinder form paragraph

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35

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U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoiner in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoiner.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:
- The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

- A. Claims 1, 2, 4 and 7 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter

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which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1-3 stand rejected for the following:

It is apparent that the strain(s) is/(are) required to practice the claimed invention(s) as recited in the claims. As a required element it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If it is not so obtainable or available, the enablement requirements of 35 U.S.C. 112, first paragraph, may be satisfied by a deposit of all strains. See 37 C. F. R. 1.802.

The specification does not provide a repeatable method for obtaining the strain(s) and it does not appear to be a readily available material. Deposit of the strain(s) would satisfy the enablement requirements of 35 U.S.C. 112. If a deposit has been made, Applicant is required to meet the necessary criteria of the deposit rules in accordance with 37 CFR 1.801-37 CFR 1.809.

If a deposit has not been supplied or made under the Budapest Treaty, then an affidavit or declaration by Applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made under the terms of the Budapest Treaty and that all restrictions imposed by the depositor on the

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availability to the public of the deposited material will be irrevocably removed upon the granting of a patent, would satisfy the deposit requirements, See 37 CFR 1.808.

If a deposit is not made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made at an acceptable depository and that the following criteria have been met:

- a) during the pendency of the application, access to the deposit will be afforded to one determined by the Commissioner to be entitled thereto;
- b) all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent;
- c) the deposit will be maintained for a term of at least thirty (30) years and at least five (5) years after the most recent request for the furnishing of a sample of the deposited material;
- d) a viability statement in accordance with the provisions of 37 CFR 1.807;

and

e) the deposit will be replaced should it become necessary due to inviability, contamination or loss of capability to function in the manner described in the specification.

In addition, the identifying information set forth in 37 CFR 1.809(d) should be added to the specification, See 37 CFR 1.803-37 CFR 1.809 for additional explanations of these requirements.

Applicant is required to be in full compliance with U.S. Rules of Deposits with respect to the availability of the strain. Upon receipt of a statement pertaining to the above (b): that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent. This requirement is a difference between the U.S. Rules and the Budapest Treaty. Upon receipt of statement pertaining to the availability, the above rejection will be withdrawn.

B.

Claims 1, 2, 4 and 7 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The broad claims lack sufficient description to inform a skilled artisan that applicant was in possession of the claimed invention at the time of filing since the specification lack the description requirement as required in the specification with respect to the taxonomic and morphological properties, see e.g. U.S. 5,695,951, columns 7-11 for appropriate properties.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1, 2, 4 and 7 are rejected under 35 U.S.C. 112, second paragraph, as 8
being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The courts have also indicated that before claimed subject matter can properly be compared to the prior art, it is essential to know what the claims do in fact cover. See, e.g., the following decisions: **In re Steele**, 305 F 2d. 859, 134 USPQ 292 (CCPA 1962); **In re Moore** 439 F 2d. 1232, 169 USPQ 236 (CCPA 1969); **In re Merat**, 519 F 2d. 1390, 186 USPQ 471 (CCPA 1975).

Claims 1, 2, 4 and 7 fail to comply with the above decisions since the specification lacks suitable descriptive information to compare the prior art with the claimed subject matter. The use of the microorganism is not sufficient to claim the microorganism since the new use of a possible old microorganism is not patentable subject matter.

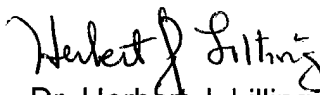
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6. A search and examination of the claimed subject cannot be properly evaluated without the required intrinsic properties of the microorganism(s) per se. There are over 500 patents containing a Burkholderia species as well as a number of Pseudomonas sp which were previously named Burkholderia. There are also a vast number of non-patent literature containing Burkholderia and previously named Burkholderia microorganisms which comparison requires Applicant to be in full compliance with the claimed properties in the defective specification.

7. **No claim is allowed.**

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Examiner Lilling whose telephone number is (703) 308-2034** and **Fax Number** is for applications **Before Final** (703) 872-9306 and **After Final** for applications is 703-872-9307 or SPE Michael Wityshyn whose telephone number is (703) 308-4743. Examiner can be reached Monday-Thursday from about 5:30 A.M. to about 3:00 P.M. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

H.J.Lilling: HJL
(703) 308-2034
Art Unit **1651**
December 1, 2003


Dr. Herbert J. Lilling
Primary Examiner
Group 1600 Art Unit 1651